UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,123	09/06/2001	Hiroaki Nakagami	213445US0PCT	6130

22850 7590 05/21/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,123	Applicant(s) NAKAGAMI ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Priority Papers, the Preliminary Amendment A, and the Information Disclosure Statement, received by the Office September 6, 2001, November 1, 2001, and December 7, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO93/17667 to Yajima *et al.*.

Yajima *et al.* disclose a composition for oral preparation, which comprises a complex formed by dispersing or dissolving an unpleasantly tasting drug and a polymer in a substance having a low melting point, and a sugar alcohol (abstract). Yajima *et al.* teach that the composition is excellent in masking unpleasantly tasting drugs and has excellent performance in biological use. More specifically, Yajima *et al.* teach that the unpleasantly tasting drug can be erythromycin, or clarithromycin, among others (page 4, paragraph 2). Yajima *et al.* teach that the substance having a low melting point if a water-insoluble or water sparingly soluble substance with a melting point of 40 to 120 degrees Celsius (page 4, paragraph 5), for example,

hydrogenated oil, stearyl alcohol, glycerin fatty acid ester (page 5, paragraph 1). Yajima *et al.* also teach that the sugar alcohol includes sorbitol, xylitol, and maltitol (page 5, paragraph 3), and that it is present at between 10 and 70 % by weight (page 5, paragraph 4). Yajima *et al.* also teaches the process of granulation through spray drying (see examples 1-13). Lastly, Yajima *et al.* teaches the composition as a dosage form for oral preparations. Therefore, the teachings of Yajima *et al.* anticipate applicant's instant claims.

Yajima *et al.* are discussed above as teaching a composition for oral preparation which comprises a unpleasantly tasting drug, a substance with a low melting point, and a sugar alcohol.

Yajima *et al.* do not specifically teach each and every one of applicant's claimed active agents. However, Yajima *et al.* does teach some of the actives claimed by applicant. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use any active which is known to have an unpleasant taste, in a formulation whose sole purpose is to mask the unpleasant taste of the active agent. The expected result would be a dosage form without an unpleasant taste.

Additionally, Yajima *et al.* do not teach the specific particle size of the granulated product. It is the position of the examiner that one of ordinary skill in the art would have been motivated to create a granulated product, with taste masking capabilities, regardless of the particular particle size, based on the teachings of Yajima *et al.*. The reference clearly teaches the process of granulation (See examples 1-13), and absent a clear showing of criticality, the determination of the particular particle size is within the skill of the ordinary worker as part of the process of normal optimization. The expected result would be a successful granulated dosage form with taste masking capabilities.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. The examiner is confused by much of Applicant's response. Applicant states "[i]t should be noted that the rejection is based on the English translation of the Abstract of Yakima *et al.* and not the full English transaction." This is simply not the case. The rejections set forth in the non final action are based on the Yajima *et al.* reference as a whole. This is evidence by the citations within the rejection pointing to particular passages in the specification of the document.

Applicant further states, "Applicants are entitled to request the Examiner to provide Applicants with a full English translation of a reference that the Examiner cites the Abstract thereof." Applicant has provided case law to support that such a request is proper. The examiner points out that the reference relied upon by the Examiner was actually cited by Applicant on the 1449 (paper number 5, filed December 12, 2001). Therefore, as the reference was originally cited by Applicant, the examiner did not provide a copy of the reference with the original office action. However, as a courtesy to Applicant, the examiner has enclosed a photocopy of the Yajima *et al.* reference.

Applicant also states that any additional action should be a non-final office action, because the Abstract of Yajima *et al.* cannot possibly be enabled since it is a separate entity from the disclosure and does not provide any motivation and/ or guidance to obtain the claimed invention. This argument is not persuasive and is rendered moot because, as stated above, the Examiner did rely on the entire Yajima *et al.* reference, so there is no need for a discussion of whether or not the abstract is enabled.

Applicant additionally argues that Yajima *et al.* fails to provide motivation to optimize the composition disclosed therein to have a particle size of from about 50 to 200 microns, and have the ability to flow through a tube having a diameter of at most 1 mm without clogging. The examiner agrees that Yajima *et al.* do not teach a particular particle size, resulting in the withdrawal of the anticipation rejection. However, it is the position of the examiner that particle size is a parameter of granular compositions which is known by the ordinary skilled worker to be manipulatable during the process of normal optimization. Absent unexpected results or a showing of criticality based solely on the size limitation, the insertion of particle size into a claim does not render the claim patentable over a similar composition, known to be granular, but silent to the particular particle size.

For these reasons, the rejection above is maintained and made final.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
May 16, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1